

UNCLASSIFIED

AD NUMBER

ADB233374

NEW LIMITATION CHANGE

TO

Approved for public release, distribution
unlimited

FROM

Distribution authorized to U.S. Gov't.
agencies only; Proprietary Information;
Sep 97. Other requests shall be referred
to U.S. Army Medical Research and Materiel
Command, 504 Scott St., Fort Detrick, MD
21702-5012.

AUTHORITY

USAMRMC Ltr., 10 Aug 98

THIS PAGE IS UNCLASSIFIED

AD _____

MIPR NUMBER 95MM5605

TITLE: Efficacy of Detection of Intraocular and Ocular Adnexal Plastic Foreign Bodies by Magnetic Resonance (MR) and Computed Tomography (CT) Imaging in the Goat.

PRINCIPAL INVESTIGATOR: MAJ Lilia A. Fannin

CONTRACTING ORGANIZATION: Madigan Army Medical Center
Tacoma, WA 98431-5000

REPORT DATE: September 1997

DTIC QUALITY INSPECTED 2

TYPE OF REPORT: Final

PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Distribution authorized to U.S. Government agencies only (proprietary information, Sep 97). Other requests for this document shall be referred to U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

19980219 154

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE September 1997	3. REPORT TYPE AND DATES COVERED Final (16 Mar 95 - 31 Dec 96)
4. TITLE AND SUBTITLE Efficacy of Detection of Intraocular and Ocular Adnexal Plastic Foreign Bodies by Magnetic Resonance (MR) and Computed Tomography (CT) Imaging in the Goat		5. FUNDING NUMBERS MIPR No. 95MM5605
6. AUTHOR(S) MAJ Lilia A. Fannin		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Madigan Army Medical Center Tacoma, WA 98431-5000		8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick Frederick, MD 21702-5012		10. SPONSORING/MONITORING AGENCY REPORT NUMBER
11. SUPPLEMENTARY NOTES		
12a. DISTRIBUTION / AVAILABILITY STATEMENT Distribution authorized to U.S. Government agencies only (proprietary information, Sep 97). Other requests for this document shall be referred to U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, Maryland 21702-5012.		12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200) PURPOSE: Determine efficacy of CT and MR in detecting plastic foreign bodies (FB's) in a live goat model. METHODS: Plastic land mine FB's were surgically implanted in 12 study eyes and orbits. 12 control eyes were surgically manipulated with no plastic implanted. Plain film, CT and MR studies were performed. CT and MR studies were with and without intravenous contrast. Masked evaluators assessed images. RESULTS: True positive FB detection in plain film was 0.5%. True positive FB detection in study eyes was 30% by CT and 34% by MR ($p=0.3664$). False negative rate was 70% (CT) and 66% (MR) ($p=0.3664$). FB's were frequently misidentified in control eyes. The addition of contrast did not significantly affect FB detection. CONCLUSION: Plain film, CT and MR inadequately detect intraocular and intraorbital plastic FB's. The addition of contrast does not improve efficacy.		
14. SUBJECT TERMS Ocular Trauma, Plastic Foreign Bodies, Anti-personnel land mines.		15. NUMBER OF PAGES 17
16. PRICE CODE		
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified
20. LIMITATION OF ABSTRACT Limited		

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army.

Where copyrighted material is quoted, permission has been obtained to use such material.

Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

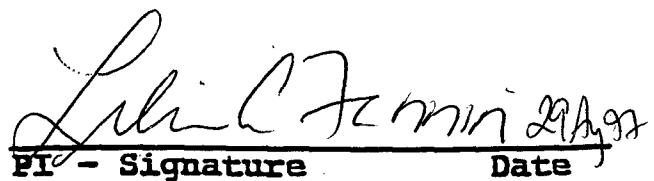
In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories. . . .


Lili J. Zemini 29 Aug 97
PI - Signature Date

FINAL REPORT

EFFICACY OF DETECTION OF INTRAOCULAR AND OCULAR ADNEXAL PLASTIC FOREIGN BODIES BY MAGNETIC RESONANCE (MR) AND COMPUTED TOMOGRAPHY (CT) IMAGING IN THE GOAT

Author: MAJ Lilia A. Fannin, MD

TABLE OF CONTENTS

	<u>Page</u>
Introduction	1
Materials and Methods	2-3
Results	4
Conclusions	5
References	6
Tables	7-13

INTRODUCTION

Ocular injuries are common with an estimated occurrence of 2.4 million eye injuries in the US annually, with approximately 60,000 admissions for ocular trauma. A growing source of potential eye trauma comes from anti-personnel land mines. Modern day land mines are made of plastic, are widely scattered around the world and are not biodegradable. Because these munitions have become common, there is now a high risk of eye injuries from plastic intraocular or ocular adnexal foreign bodies within the civilian population.

Despite the fact that CT and MR are powerful diagnostic tools in the evaluation of eye trauma, review of the literature shows difficulty in the detection of plastic ocular foreign bodies with MR and CT (1, 2, 3). There are no controlled studies in the medical literature which evaluate the efficacy of CT or MR imaging in the detection of ocular plastic foreign bodies, nor are there any studies which evaluate the use of contrast in detecting plastic foreign bodies. This study evaluates the efficacy of CT and MR imaging of ocular plastic foreign bodies in a goat model.

MATERIALS AND METHODS

Plastic foreign bodies from one of two different types of unused land mines were surgically implanted in the study eye of 12 live goats. The fellow eye was the control. The number of plastic foreign bodies ranged from one to six. The placement sites included the globe and ocular adnexa. The plastic foreign bodies ranged in size, 0.5 mm - 3 mm. The type for foreign body implanted, the number of foreign bodies implanted, the study eye (right or left) and position of implantation were randomly selected (Table 1). The control eye was surgically manipulated in a similar manner to that of the study eye; however, no foreign bodies were implanted.

CT, MR and plain film imaging were performed immediately after implantation of foreign bodies. Standard orbital trauma CT protocol of 3 mm cuts and standard trauma MR protocol was implemented. CT and MR imaging was performed without and with intravenous contrast. Plain film AP and lateral x-rays were then obtained.

The study animals were under general anesthesia throughout the study and the study animals were euthanized immediately after completion of radiographic studies.

Each study animal had 7 "sets" of images (Table 2):

- Set 1: Plain film x-ray (AP and lateral)
- Set 2: CT without contrast, axial
- Set 3: CT without contrast, axial and coronal
- Set 4: CT with and without contrast, axial and coronal
- Set 5: MR without contrast, axial
- Set 6: MR without contrast, axial and coronal
- Set 7: MR with and without contrast, axial and coronal

The image sets were evaluated by four masked physicians. The study and control eye images were evaluated separately. Each evaluator reported the number of foreign bodies detected in each imaging set (Table 3).

RESULTS

A total of 180 foreign bodies could possibly be identified from all of the imaging sets. Nine foreign bodies were identified by plain film, 81 by CT without contrast (axials), 91 by CT without contrast (axials and coronals), 83 by CT with and without contrast (axials and coronals), 93 by MR without contrast (axial), 97 by MR without contrast (axials and coronals), 96 by MR with and without contrast (axials and coronals). (Table 4)

True positive FB detection by plain film was 0.5%. True positive FB detection was 25% by CT without contrast (axials) and 30% by CT without contrast (axials and coronals). True positive FB detection was 37% by MR without contrast (axials) and 34% by MR without contrast (axials and coronals) ($p=0.3664$). With the addition of contrast, the true positive FB detection was 25% and 36% respectively for CT and MR.

Plastic foreign bodies were misidentified in the control eyes in all of the radiographic studies. Eight were misidentified by plain film, 36 by CT without contrast (axials), 37 by CT without contrast (axials and coronals), 38 by CT with and without contrast (axials and coronals), 26 by MR without contrast (axial), 35 by MR without contrast (axials and coronals), 32 by MR with and without contrast (axials and coronals).

Detection of plastic foreign bodies by CT and MR was statistically significant when compared to plain film(0.0000). There was no statistical significance between CT and MR imaging. Intravenous contrast did not significantly improve the detection of plastic foreign bodies.

Two goats expired prior to completing MR requiring contrast.

CONCLUSIONS

The assessment of an ocular and orbital plastic foreign body can be a clinical challenge. The mechanism of injury may lead to a high suspicion of a foreign body, however, physical exam may not reveal the foreign body. Clinicians often rely on imaging studies to detect an occult plastic foreign body.

The presence of a plastic foreign body usually demands surgery to remove it. If a plastic foreign body is undetected, a patient may be exposed to possible blinding complications from an occult plastic foreign body. If a plastic foreign body is falsely detected by an imaging study, the patient may undergo unnecessary surgery which may also lead to blindness from surgical complications.

This study demonstrates the difficulty in detecting ocular and orbital plastic foreign bodies. CT and MR are clearly more efficacious in detecting plastic foreign bodies than by plain film. However CT and MR images may not always reveal the plastic foreign bodies and the images may produce findings that are misinterpreted as foreign bodies. More foreign bodies were found by MR than by CT but this was not statistically significant. The addition of coronal views and the addition of radiographic contrast did not improve the detection of foreign bodies.

In conclusion, plain film studies are not reliable in the detection of plastic foreign bodies. CT and MR can detect the presence of plastic foreign bodies, however, the efficacy of these studies are less than 38%. The addition of coronal views and the addition of contrast for CT or MR does not improve efficacy. Despite the low efficacy in detecting plastic foreign bodies, CT and/or MR should be used to evaluate ocular trauma.

REFERENCES

1. Henrikson, Mafee, Flanders, Kriz, Peyman: CT evaluation of plastic intraocular foreign bodies. *AJNR*: 8:378-9, 1987.
2. Lobue, Deutsch, Lobick, Turner: Detection and localization of nonmetallic intraocular foreign bodies by Magnetic resonance imaging. *Arch Ophthalmol*: 106:260-261, 1988.
3. Duker, Fischer: Occult plastic intraocular foreign body. *Ophth Surg*, 20(3): 169-170.

TABLE 1.

GOAT	STUDY EYE	NUMBER OF FB's	TYPE OF FB
1	right	4	beige
2	right	3	black
3	right	3	beige
4	left	4	beige
5	left	5	black
6	right	2	black
7	right	2	beige
8	left	1	beige
9	right	6	beige
10	left	4	beige
11	left	5	beige
12	left	6	beige

TABLE 2. Description of Radiographic Set Types

SET TYPE	IMAGING MODALITY
1	Plain Film
2	CT, no contrast, axials
3	CT, no contrast, axials & coronals
4	CT, with contrast, axials & coronals
5	MR, no contrast, axials
6	MR, no contrast, axials & coronals
7	MR, with contrast, axials & coronals

TABLE 3. Foreign Bodies Detected by the Four Masked Evaluators.

SET	GOAT	SET TYPE	EYE	NUMBER OF FB's	MAZZOLI	AINBINDER	ROVIRA	COUGHLIN
1	11	6	L	5	2	2	5	2
2	4	5	L	4	2	2	2	2
3	8	1	L	1	0	0	0	0
4	12	1	L	6	0	0	0	0
5	7	2	L	0	0	1	0	0
6	5	5	L	5	3	2	3	3
7	9	3	L	0	0	2	0	0
8	6	4	R	2	2	2	3	2
9	6	6	L	0	0	0	0	0
10	1	4	R	4	1	2	1	1
11	5	2	R	0	0	0	0	0
12	11	2	L	5	1	1	1	0
13	5	1	L	5	0	0	0	0
14	5	3	R	0	0	0	0	0
15	1	7	R	4	4	3	4	1
16	1	3	R	4	2	1	1	1
17	6	3	L	0	0	0	0	0
18	10	3	L	4	1	1	1	1
19	3	5	L	0	1	1	1	1
20	3	1	L	0	0	0	0	0
21	5	6	R	0	0	0	1	0
22	11	4	L	5	1	2	1	1
23	6	1	L	0	0	0	1	0
24	12	4	R	0	0	2	1	0
25	8	5	L	1	1	1	0	1
26	10	5	L	4	2	1	1	1
27	7	4	L	0	0	2	0	0
28	12	3	L	6	2	3	3	2
29	1	6	R	4	4	2	3	2
30	9	7	L	0	0	0	1	1
31	9	2	L	0	1	2	0	0
32	4	6	R	0	2	2	1	2
33	8	3	R	0	0	1	0	0
34	2	6	R	3	3	3	2	3
35	8	4	R	0	0	0	0	0
36	1	5	R	4	3	2	2	1
37	1	2	L	0	0	0	0	0
38	6	2	R	2	2	4	2	2
39	7	5	L	0	0	0	0	0
40	10	2	L	4	0	4	1	1
41	8	2	L	1	0	1	0	0
42	11	3	L	5	1	4	1	1
43	7	6	R	2	1	1	2	1
44	10	4	L	4	1	2	0	1
45	4	2	L	4	1	1	1	0

TABLE 3. continued

TABLE 3. continued

SET	GOAT	RAD TYPE	EYE	# FB's	MAZZOLI	AINBINDER	ROVIRA	COUGHLIN
1	11	6	r	0	2	2	2	2
2	4	5	r	0	2	2	3	2
3	8	1	r	0	0	0	1	0
4	12	1	r	0	0	0	2	0
5	7	2	r	2	0	1	1	0
6	5	5	r	0	0	1	1	0
7	9	3	r	6	1	5	1	0
8	6	4	l	0	0	0	0	0
9	6	6	r	2	4	2	2	2
10	1	4	l	0	0	1	1	0
11	5	2	l	5	5	4	4	5
12	11	2	r	0	1	2	2	1
13	5	1	r	0	0	0	0	0
14	5	3	l	5	6	5	3	3
15	1	7	l	0	1	1	1	0
16	1	3	l	0	0	1	2	0
17	6	3	r	2	2	3	2	2
18	10	3	r	0	0	5	0	0
19	3	5	r	3	1	1	2	1
20	3	1	r	3	0	0	0	0
21	5	6	l	5	3	2	4	2
22	11	4	r	0	1	1	2	1
23	6	1	r	2	0	0	0	0
24	12	4	l	6	2	2	3	2
25	8	5	r	0	0	0	0	0
26	10	5	r	0	0	0	0	0
27	7	4	r	2	0	2	2	0
28	12	3	r	0	0	3	0	0
29	1	6	l	0	1	1	2	0
30	9	7	r	6	3	2	1	1
31	9	2	r	6	2	4	0	1
32	4	6	l	4	2	2	2	2
33	8	3	l	1	0	1	0	0
34	2	6	l	0	0	0	0	0
35	8	4	l	1	0	0	0	0
36	1	5	l	0	1	1	1	0
37	1	2	r	4	2	2	2	1
38	6	2	l	0	0	0	0	0
39	7	5	r	2	1	2	1	1
40	10	2	r	0	0	4	0	0
41	8	2	r	0	0	2	1	0
42	11	3	r	0	1	2	3	1
43	7	6	l	0	0	0	0	0
44	10	4	r	0	0	4	0	0
45	4	2	r	0	2	1	3	2

TABLE 3. continued

46	12	6	1	6	2	4	3	2
47	3	7	1	0	1	2	3	1
48	6	7	1	0	0	0	0	0
49	11	7	r	0	1	3	2	2
50	5	4	1	5	5	6	4	5
51	12	7	r	0	0	0	0	0
52	2	2	1	0	0	0	0	0
53	4	4	1	4	1	1	2	1
54	2	3	1	0	0	0	0	0
55	6	5	r	2	2	2	4	2
56	3	2	r	3	0	1	0	0
57	7	3	r	2	0	2	2	1
58	3	3	1	0	1	2	4	1
59	12	5	1	6	2	4	4	2
60	4	3	1	4	0	3	4	1
61	9	4	1	0	0	4	0	0
62	7	7	r	2	1	2	2	1
63	10	1	1	4	0	0	1	0
64	1	1	1	0	0	0	0	0
65	2	7	1	0	0	0	1	0
66	3	4	r	3	0	1	0	0
67	9	6	1	0	0	0	2	0
68	10	7	1	4	3	1	3	1
69	8	6	1	1	1	0	1	0
70	4	1	1	4	0	0	0	0
71	7	1	1	0	0	0	0	0
72	3	6	r	3	1	1	2	1
73	9	5	r	6	2	1	4	1
74	4	7	1	4	0	3	5	2
75	2	4	r	3	3	5	4	3
76	2	5	1	0	0	0	0	0
77	12	2	1	6	3	3	2	3
78	11	1	1	5	0	0	0	0
79	11	5	1	5	1	2	2	2
80	10	6	1	4	1	2	2	1
81	5	7	1	5	2	4	3	3
82	8	7	r	0	0	0	1	0
83	2	1	r	3	0	0	0	0
84	9	1	1	0	0	0	0	0

TABLE 4.

SET	IMAGING MODALITY	TOTAL FB's	TRUE + and FALSE +	FALSE +	TRUE +
TYPE		IMPLANTED			
1	Plain Film	180	9	8	1
2	CT, no contrast, axials	180	81	36	45
3	CT, no contrast, axials & coronals	180	91	37	54
4	CT, with contrast, axials & coronals	180	83	38	45
5	MR, no contrast, axials	180	93	26	67
6	MR, no contrast, axials & coronals	180	97	35	62
7	MR, with contrast, axials & coronals	180	96	32	64



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO
ATTENTION OF:

MCMR-RMI-S (70-1y)

10 Aug 98

MEMORANDUM FOR Administrator, Defense Technical Information Center, ATTN: DTIC-OCP, Fort Belvoir, VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for the following contracts. Request the limited distribution statement for these contracts be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

<u>Contract Number</u>	<u>Accession Document Number</u>
DAMD17-91-C-1020	ADB187724 +✓
DAMD17-92-C-2053	ADB196427 +
DAMD17-94-C-4022	ADB190750 +
DAMD17-94-C-4023	ADB188373 +
DAMD17-94-C-4027	ADB196161 +✓
DAMD17-94-C-4029	ADB190899 +
DAMD17-94-C-4039	ADB188023 +
DAMD17-94-C-4024	ADB189184 +
DAMD17-94-C-4026	ADB187918 +
DAMD17-94-J-4250	ADB221970
DAMD17-94-J-4250	ADB230700
DAMD17-96-1-6241	ADB233224
DAMD17-96-1-6241	ADB218632 ✓
DAMD17-94-J-4496	ADB225269
DAMD17-94-J-4392	ADB225308 ✓
DAMD17-94-J-4455	ADB225784 ✓
DAMD17-94-J-4309	ADB228198 ✓
DAMD17-91-C-1135	ADB233658 ✓
DAMD17-94-J-4038	ADB232313 ✓
DAMD17-94-J-4073	ADB222794 ✓
DAMD17-94-J-4131	ADB219168 ✓
DAMD17-94-J-4159	ADB232305 ✓
MIPR 95MM5535	ADB232218 ✓
95MM5605	ADB233374
95MM5673	ADB226037

MCMR-RMI-S

SUBJECT: Request Change in Distribution Statement

2. Point of contact for this request is Ms. Judy Pawlus at DSN 343-7322 or email: judy_pawlus@ftdetrck-ccmail.army.mil.

FOR THE COMMANDER:


PHYLLIS M. RINEHART
Deputy Chief of Staff for
Information Management